IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL No. 2327**
THIS DOCUMENT RELATES TO: ETHICON WAVE 1 CASES LISTED IN EXHIBIT A	**JOSEPH R. GOODWIN U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE THE PROPOSED TESTIMONY OF JULIE DROLET, M.D.

INTRODUCTION

Defendant Ethicon, Inc., proffers the expert testimony of Julie Drolet, M.D. regarding the safety and efficacy of Ethicon's TVT-O and Prolift+M devices. The Court should exclude Dr. Drolet's opinions because: (1) she does not provide any independent analysis and, instead, merely parrots conclusory opinions from various studies and professional societies; and (2) Dr. Drolet does not disclose any expert opinions that are the subject of proper expert testimony or are the result of a reliable methodology. Accordingly, Dr. Drolet's testimony should be excluded.

LEGAL STANDARDS

Under Federal Rule of Evidence 702, expert testimony is only admissible if the expert is qualified and the testimony is (1) helpful to the trier of fact in understanding the evidence to determine a fact in use, (2) based upon sufficient facts or data, and (3) the product of reliable principles and methods that (4) have been reliably applied to the facts of the case. Fed. R. Evid. 702. Acting as the gatekeeper, the Court must ensure that all expert testimony is "not only relevant, but reliable." *Cooper v. Smith & Nephews, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001)

(internal citation omitted).[1] The proponent of the expert testimony has the burden to "come forward with evidence from which the court can determine that the preferred testimony is properly admissible. *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

ARGUMENT

I. DR. DROLET FAILS TO PERFORM ANY INDEPENDENT ANALYSIS OF THE SCIENCE AND DATA AND INSTEAD MERELY PARROTS CONCLUSIONS FROM VARIOUS STUDIES AND PROFESSIONAL SOCIETIES.

In her 49-page report, Dr. Drolet offers very little that can be construed as general causation opinions. Instead, the majority of her report is filled with a narrative summary about the medical conditions of pelvic organ prolapse and stress urinary incontinence, a limited description of the history of treatments for these diseases, and a sporadic discussion of various scientific studies, without any analysis as to how the studies were chosen or evaluated. The bulk of Dr. Drolet's Report is a case-specific analysis of a specific plaintiff's medical records.

Dr. Drolet does not offer an opinion regarding the complication or efficacy rates associated with the Prolift+M or TVT-O products. Instead she selectively cites various findings in a narrative fashion. Her testimony is therefore not "helpful to the trier of fact in understanding the evidence to determine a fact in use." Fed. R. Evid. 702.

For example, in her Report, Dr. Drolet states, "Midurethral slings offer a greater improvement in quality of life domains compared to Burch surgeries (Ogah 2009)."[2] While this may in fact be a finding from the Ogah 2009 Cochrane review, this bald assertion is devoid of any explanation as to why Dr. Drolet discounted other studies, why Dr. Drolet found this study more compelling, or any explanation as to what measures of actual quality of life Dr. Drolet

[1] As the Court has pointed out, "this gatekeeper role take an on extraordinary significance" in this litigation with more than 60,000 cases regarding surgical mesh products. *Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *2 n.3 (S.D. W. Va. Aug. 18, 2014) (Goodwin, J.).
[2] Report at 11 (Report of Julie Drolet, M.D., attached As Exhibit B).

found compelling in this study. In fact, this one sentence comprises the entire paragraph supporting this "opinion." Dr. Drolet repeats this conclusory parroting of studies and other papers throughout her Report.

Dr. Drolet also offers a narrative recitation of various position statements and public notifications from industry organizations, urological associations, and the FDA. For example, Dr. Drolet makes the assertion that, "It is now undeniable that mid urethral slings have a very acceptable risk/benefit profile."[3] Dr. Drolet then states that AUGS, SUFU, and other organizations have reached certain conclusions regarding the usage of midurethral slings for treating stress urinary incontinence. Without some discussion of contrary literature or a more detailed analysis of the science or data, Dr. Drolet's opinion amounts to nothing more than regurgitation of the opinions of certain organizations. The jury is capable of evaluating these position statements without the assistance of Dr. Drolet.

II. DR. DROLET'S OPINIONS REGARDING THE RISK BENEFIT PROFILE OF TVT-O AND PROLIFT+M ARE CONTRADICTED BY THE SCIENCE SHE CITES AND HER OWN EXPERIENCE AND ARE THEREFORE UNRELIABLE.

Dr. Drolet's has not disclosed a reliable basis for her conclusion regarding the risk benefit profile of the products at issue. Dr. Drolet makes the generalized statement that, "[t]he benefits of Prolift+M and TVT-O outweighed the risks, and this was certainly the case in October of 2009."[4] However, on the next page of her Report, Dr. Drolet cites a 2011 committee opinion from the American College of Obstetrician and Gynecology (ACOG) that states, "POP [pelvic organ prolapse] vaginal mesh repair should be reserved for high risk individuals."[5] Dr. Drolet does not reconcile her generalized statement with the contradictory conclusion of ACOG that POP mesh repair should be reserved for high risk individuals.

[3] Report at 12.
[4] Report at 27.
[5] Report at 28.

Additionally, Dr. Drolet's testimony illustrates that her personal experience does not support her generalized statement regarding the risk benefit profile of Prolit+M. Dr. Drolet testified that she is unaware of any clinical benefits associated with Prolift+M as compared to Prolift. When asked why she changed from Prolift to Prolift+M, Dr. Drolet testified, "I don't specifically recall."[6] When asked whether there was some benefit with the Prolift +M as compared to Prolift, Dr. Drolet testified, "I'm not quite sure. Can't answer you."[7] Additionally, when asked if it was easier to work with the Prolift as compared to the Prolift +M, she stated, "I don't recall a specific difference."[8]

Further, Dr. Drolet testified that she is unaware of whether Prolift+M was different from Prolift, "I'm not sure if the shape of the introducer had changed or not. I can't recall."[9] Further, when asked whether she performed "some sort of a risk benefit analysis of the differences between the Prolift and Prolift +M" in her practice and in her discussions with patients, Dr. Drolet responded, "At the time, no, I did not."[10] Dr. Drolet's testimony demonstrates that she has a lack of personal knowledge regarding the Prolift+M which precludes her from relying upon "personal experience" as a basis for the opinion.

Dr. Drolet's non-systematic review of the medical literature also does not provide a reliable basis for reaching her opinion regarding the risk benefit profile of the products at issue. While Dr. Drolet does sporadically discuss various complications and studies throughout her report, she has not disclosed any reliable methodology with which she reviewed the literature, decided which studies to cite, or explained why she discounted other studies. Accordingly, Dr. Drolet's opinion regarding the risk benefit profile of Prolift+M and TVTO should be excluded.

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[6] Drolet dep. 3/31/2016 10:05 a.m. 75:13-15 (Deposition of Julie Drolet, M.D., attached as Exhibit C).
[7] Drolet dep. 3/31/2016 10:05 a.m. 75:16-20.
[8] Drolet dep. 3/31/2016 10:05 a.m. 35:3-9.
[9] Drolet dep. 3/31/2016 10:05 a.m. 78:19-22.
[10] Drolet dep. 3/31/2016 10:05 a.m. 83:13-19.

III. DR. DROLET'S OPINIONS REGARDING THE STATE OF MIND OR KNOWLEDGE OF OTHER DOCTORS ARE UNRELIABLE AND SHOULD BE EXCLUDED.

In her report, Dr. Drolet repeatedly opines that certain complications were well known to "all" physicians. For example, Dr. Drolet states that various risks such as erosions and exposures "have been well known to gynecologists, urogynecologists, and urologists who operate in the pelvic floor."[11] She then makes the broad statement that, "These risks are also well known as they have been described extensively in the peer-reviewed medical literature."[12] Dr. Drolet provides no basis for how she determined which physicians are aware of various studies from dozens of different journals. Numerous additional examples of Dr. Drolet improperly opining regarding the state of mind or knowledge of "all physicians" include the following:

1. "Nowadays many gynecologists and urogynecologists believe that the high recurrence rate may result from failure to address the descent of the uterus or vaginal vault concomitantly. "[13]

2. "Most pelvic floor surgeons consider level 1 support critical in the long term success in maintaining the appropriate distribution of forces within the pelvis as well as prevention of recurrences of the initial surgery along with prevention of other compartment failures (Withagen, 2010)."[14]

3. "No matter the approach, all gynecologists are or should be aware of the surgical risks such as bleeding, infection, injury to nerves, organs and vessels, and post-operative risks…"[15]

4. "A reasonably prudent pelvic floor surgeon performing incontinence and prolapse surgeries would have already been aware of the potential for these complications..."[16]

5. "Pelvic floor surgeons would know of the risks associated with any surgery including pain and dyspareunia by way of their basic medical

[11] Report at 16.
[12] *Id.*
[13] Report at 8.
[14] Report at 8.
[15] Report at 9.
[16] Report at 18.

education and training. They would also know that pain and dyspareunia are potential risks …"[17]

6. "Pelvic floor surgeons who would have the licensing, credentials, and privileges to perform the Prolift & Prolift+M and TVT-O procedures would be aware of the risks and complications that can occur with any pelvic surgery."[18]

7. "Pelvic floor surgeons would be aware of such risks, and should be confident in their ability to manage complications from the procedures they feel competent to perform…"[19]

8. "…complications such as urinary problems, incontinence or retention, dyspareunia, pain and scarring are well-known complications that can occur with any pelvic floor surgery…"[20]

9. "Experienced pelvic floor surgeons such as Dr. Ehsani, in her fellowship, would be aware of the frequency and severity of complications…"[21]

All of these statements regarding what doctors knew or should know should be excluded, and Dr. Drolet should be precluded from testifying about the state of mind or knowledge of "any" or "all" physicians.

IV. DR. DROLET'S OPINIONS REGARDING THE INTENT OF INDUSTRY OR THE FDA ARE UNRELIABLE AND IRRELEVANT.

Dr. Drolet repeatedly opines about what Ethicon knew or its intent regarding certain actions. These are not proper subjects for expert testimony, and Dr. Drolet has not established a reliable methodology for reaching any of these opinions.

For example, in her Report, Dr. Drolet states, "The introduction of mesh in the treatment of pelvic organ prolapse was intended to attain an important goal for surgeons – improve the longevity of the repair."[22] Dr. Drolet fails to explain how she reached this conclusion.

[17] Report at 18.
[18] Report at 27.
[19] Report at 27.
[20] Report at 27.
[21] Report at 28.
[22] Report at 16.

Moreover, such an opinion is improper expert testimony regarding corporate intent. Other examples of Dr. Drolet's assumptions regarding Ethicon's intentions include:

1. "The Prolift+M was eventually developed by Ethicon in order to continue innovation, continue to maintain efficacy and durability…"[23]

2. "Overall the design of the Posterior Prolift and Prolift+M not only made sense, but it was consistent with the decades-long march towards optimizing correction of prolapse…"[24]

Additionally, Dr. Drolet also improperly opines on the FDA's intent when it issued Public Health advisories. She opines, "Pelvic floor surgeons were the target audience of this notification and would have been expected to read and consider the notice."[25]

None of these statements are proper subjects for expert testimony. Dr. Drolet has not established that any of these opinions are the product of reliable methodology. Accordingly, these opinions should be excluded, and Dr. Drolet should be precluded from testifying as to the intent or knowledge of Ethicon or the FDA.

V. DR. DROLET'S OPINIONS REGARDING THE FDA'S 510(K) PROCESS DEMONSTRATE SHE IS NOT QUALIFIED TO OPINE ON THE SAFETY OF PELVIC FLOOR DEVICES.

Ethicon has offered Dr. Drolet as an expert to testify regarding the safety and efficacy of the TVT-O and Prolift+M devices. When asked what the bases were for her opinions that the devices were safe and effective, Dr. Drolet testified that one of the bases of her opinions was the fact that the FDA cleared the devices for sale. When asked whether she believed that the FDA's clearance of a medical device for marketing under the 510(k) process meant that the FDA has

[23] Report at 17.
[24] Report at 28.
[25] Report at 17.

made a determination that the device is safe and effective for its intended use, Dr. Drolet testified, "At the time that they cleared it, I would say yes."[26]

As the Court knows, FDA clearance is not equivalent to a finding that the device is safe and effective – merely that it is substantially equivalent to a predicate device. Dr. Drolet's complete misunderstanding of the FDA's role and the fact that this misunderstanding is the basis of her primary opinion demonstrates that her opinions are utterly unreliable and should be excluded.

VI. DR. DROLET'S OPINIONS REGARDING THE INSTRUCTIONS FOR USE (IFU) ARE UNRELIABLE.

Dr. Drolet admitted that she is not qualified to act as a regulatory expert and repeatedly testified that she is not aware of the regulations or rules that govern the content of an IFU. For example, she testified as follows: "I don't know what is necessary by FDA standards in the formulation of an IFU…."[27] In addition, she testified that she had never reviewed Ethicon's internal procedures or documents concerning the contents of an IFU. Despite this total lack of information and knowledge, Dr. Drolet opines that it would not be appropriate to include all of the known risks and complications in the IFU because it would be too long. For example, Dr. Drolet makes the broad statement that "it would be almost impossible for a manufacturer to list the exact frequency and severity of dyspareunia in the IFU."[28] Dr. Drolet's opinions regarding the adequacy of the IFU are simply made up, are not the product of a reliable methodology nor based on any reliable data or facts and should be excluded.

[26] Drolet, 3/31/2016 10:05 a.m. 88:19-89:4.
[27] Drolet, 3/31/2016 1:28 p.m. 78:19-22 (Deposition of Julie Drolet, M.D., attached as Exhibit D).
[28] Report at 19.

VII. DR. DROLET'S LEGAL CONCLUSIONS SHOULD BE EXCLUDED.

Dr. Drolet improperly offers legal conclusions under the guise of expert testimony. For example, in her report, Dr. Drolet concludes that the Prolift+M IFU and the TVT-O IFU "adequately warned pelvic surgeons."[29] Of course, the determination regarding the adequacy of the warnings is an issue for the jury. This Court has correctly and repeatedly held that legal conclusions are an improper subject for expert testimony. Dr. Drolet's opinions regarding legal conclusions should be excluded.

VIII. DR. DROLET COULD NOT IDENTIFY WHICH MATERIALS SHE ACTUALLY RELIED UPON IN FORMING HER OPINIONS.

Rule 26 requires that an expert disclose a complete statement of all opinions the witness will express and the basis and reasons for them. Fed. R. Civ. P. 26(a)(2)(B)(i). Dr. Drolet issued an expert report dated March 1, 2016, which included a 25-page list of materials she relied upon in reaching her opinions.

In her deposition, Plaintiffs attempted to identify the bases for Dr. Drolet's opinions. However, it became apparent that Dr. Drolet had not actually read, much less relied upon, many of the materials listed on her reliance list. For example, Dr. Drolet's reliance list indicates she reviewed numerous expert reports issued in the Ethicon mesh litigations. However, she testified that she had not reviewed at least ten of the expert reports that were listed on her reliance materials.[30] In fact, she could not identify which documents she had not reviewed. She testified as follows:

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[29] Report at 27 ("It is my opinion, to a reasonable degree of medical certainty, that the Prolift+M IFU along with the TVT-O IFU which incorporated and was supplemented by professional education and the surgical technique guide, adequately warned pelvic surgeons, such as Dr. Ehsani who completed a 3 year Fellowship under the guidance of Dr. Lucente, who had extensive experience with mesh, of the appropriate risks and complications related to the Prolift & Prolift+M and TVT-O.").

[30] Drolet dep. 3/31/2016 10:05 a.m. 69:8-70:9.

Q. [I]t sounds like there may be documents that were provided to you that may or may not be on your reliance list that you may or may not have had the opportunity to read. Is that fair?
A. That would be fair to say and I obviously did not use them in order to prepare this report if I didn't see them.[31]

Further, Dr. Drolet previously testified that she would have liked to, but had not, reviewed certain depositions of Ethicon corporate employees regarding the products at issue. In fact, she testified that these depositions could have been important to her when she formed her opinions. In an earlier deposition in the *Hammons* case in Philadelphia, Dr. Drolet testified as follows:

Q. Do you know who Axel Arnaud is?
A. I've heard -- or I've read his name in some documents but...
Q. Okay. Do you know that he was the scientific director of Gynecare Europe when Prolift was being designed?
A. I recall reading that.
Q. Okay. Would you like to know what he said about the design of the Prolift?
A. Do you want to read it?
Q. Well, I'm asking you, do you think that would be important when you developed your opinions?
A. It would be an element, so I would want to know.
Q. Right. And you didn't have that, correct?
A. Not that I specifically can recall. [32]
…
Q. All right. You also didn't get the deposition of James Hart?
A. I don't -- I don't think so.
Q. He was the vice president of medical operations at Ethicon when the Prolift was marketed. Would you have liked to have known what he said about the Prolift?
A. Again, I would have liked to see it in this context.[33]
…
A. I have not come across over the last few years on articles that describe this phenomenon that you say rolling and bunching as a frequent complication of mesh.
Q. If it was a known complication of mesh and there are internal documents about it, would you have liked to have considered those when coming up with your expert opinion in this case?

[31] Drolet dep. 3/31/2016 1:28 p.m. 139:16-21.
[32] Drolet dep. 11/13/2015 132:7-133:4 (Deposition of Julie Drolet, M.D., attached as Exhibit E).
[33] Drolet dep. 11/13/2015 135:2-12.

A. Yes, I would have.
Q. If there's literature out there that specifically relates to this phenomenon of the ability of the mesh to bunch up, would you have liked to have seen that when making your opinions in this case?
A. I would have liked to have seen those articles.[34]

After earlier testifying that these materials might alter her expert opinions about the Prolift device, Dr. Drolet failed to review them or even include them on her Reliance List for Prolift+M or TVT-O. She testified as follows:

Q. Did you ask for any documents as a result of the deposition in Hammons? Did you say, hey, we discussed such and so, I'd like to see that document or that study?
A. No.[35]

Dr. Drolet's admission that certain depositions and documents might alter her expert opinions and her subsequent refusal to obtain and read those documents demonstrates that her opinions are unreliable. Accordingly, Dr. Drolet's testimony should be excluded because she has not established that her opinions are the product of reliable methodology.

IX. CONCLUSION

Dr. Drolet's few general causation opinions should be excluded for the reasons set forth above. The remainder of Dr. Drolet's general report, consisting of a narrative recitation of the history of prolapse and incontinence, should also be excluded because it would not help a jury understand any facts at issue in this litigation. For these reasons, the Court should grant Plaintiffs' Motion and exclude the proffered general causation expert testimony of Julie Drolet, M.D.

[34] Drolet dep. 11/13/2015 279:4-280:15.
[35] Drolet dep. 3/31/2016 10:05 a.m. 94:20-95:1.

Respectfully submitted this 21st day of April, 2016.

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing **MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE THE PROPOSED TESTIMONY OF JULIE DROLET, M.D.,** on April 21, 2016, using the Court's CM/ECF filing system, thereby sending notice of said filing to all counsel.

/s/ Sarah Peasley
Sarah Peasley